K001078

JUN 2 3 2000

510(k) SUMMARY

Manufacturer:
Sulzer Orthopedics Ltd.
Grabenstrasse 25
CH 6341 Baar, Switzerland

US Designated Agent:
Sulzer Orthopedics Inc.
9900 Spectrum Drive
Austin, TX 78717
Tel: (512) 432-9900
Fax: (512) 432-9291

Contact:
Frances E. Harrison
Senior Regulatory Affairs Specialist

Classification Name:
Hip joint metal/ceramic/polymer semi-constrained cemented or nonporous uncemented prosthesis (21 CFR 888.353)

Common/Usual Name:
Total Hip Prosthesis

Trade/Proprietary Name:
Sulzer Orthopedics MS-30 Femoral Stem

Product Description:

The MS-30 is a highly polished metallic femoral stem manufactured from forged stainless steel alloy (Protasul S30, ISO 5832-9). It is available in six sizes. The stem is intended for cemented use only. It features a three dimensional conical wedge shape with rounded edges to assist in rotational stability, self centering in the femoral canal and creation of a favorable cement mantle. The distal portion of the stem has a hole for attachment of a PMMA distal canal centralizer. The MS-30 Stem employs a 12/14 morse type taper for attachment of a Sulzer metallic or ceramic femoral head having a 12/14 configured bore.

Intended Use/Indications for Use:

The MS-30 Femoral Stem is intended for cemented use to replace the anatomy of the femur in cases of total hip or hemi-hip replacement. It is intended to be used with Sulzer Orthopedics acetabular components and metallic or ceramic femoral heads possessing a 12/14 taper.

The indications for use of the MS-30 are for treatment of the following:

- Advanced wear of the joint due to degenerative, posttraumatic or rheumatic diseases.
- Fractures or vascular necroses.
- Status following earlier operations such as joint reconstruction (osteotomy), arthrodesis, hemiarthroplasty of total hip prosthesis (THP).

Substantial Equivalence:

The MS-30 Femoral Stem is substantially equivalent to the previously cleared MS-30 Femoral Stem as it has the same indications for use, design, materials, sterilization and method of manufacture. Testing/analysis indicated that the device would survive physiological loading.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUN 2 3 2000

Ms. Frances E. Harrison
Senior Regulatory Affairs Specialist
Sulzer Orthopedics, Inc.
9900 Spectrum Drive
Austin, Texas 78717

Re: K001078
Trade Name: Sulzer Orthopedics MS-30™ Femoral Stem
Regulatory Class: II
Product Code: JDI
Dated: April 3, 2000
Received: April 4, 2000

Dear Ms. Harrison:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general control provisions of the Act. The general control provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the current Good Manufacturing Practice requirement, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic (QS) inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4659. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or at (301) 443-6597, or at its Internet address "http://www.fda.gov/cdrh/dsmamain.html".

Sincerely yours,

Celia M. Witten, Ph.D., M.D.
Director
Division of General, Restorative and
Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number (if known): K001078

Device Name: MS-30™ Femoral Stem

Indications For Use:

The MS-30 Femoral Stem is intended for cemented use in treatment of the following:

1. Advanced wear of the joint due to degenerative, posttraumatic or rheumatic diseases.

2. Fractures or vascular necroses.

3. Status of following earlier operations, such as joint reconstruction (osteotomy), arthrodesis, hemiarthroplasty of total hip prosthesis.

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Diane R. Vochmer

(Division Sign-Off)
Division of General Restorative Devices
510(k) Number K001078

Prescription Use Y/N **OR** **Over-The-Counter Use** No

(Optional Format 1-2-96)